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510(K) SUMMARY

Lumenis ResurFX

510(k) Number K130028

Applicant's Name:

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SEP 0 3 2013

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
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Yoram@qsitemed.com

Trade Name: ***Lumenis ResurFX Laser Module***
Common Name: Laser Module

Summary Preparation Date: April 11, 2013

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: ONG
Regulation No: 21 CFR 878.4810
Class: II
Panel: General and Plastic Surgery

Device Description:

The ***ResurFX module*** is a 1565nm non ablative laser module that is an add-on to FDA cleared mainframes like the M22 (LUM 2, cleared under K083733).

The ***ResurFX module*** is constructed of:
1565nm fiber laser
Scanner and scanner controller
Power Supply
Cooling unit
Treatment handpiece
The system may be activated by either handpiece or footswitch trigger.

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Intended Use Statement:

The ***1565nm ResurFX*** laser module is indicated for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Fraxel (Solta medical) 1550 nm laser	**K091420**	Oct 14 2009
Palomar Lux1540	**K090195**	Nov 20, 2009
Palomar Icon Aesthetic System	**K110907**	June 22, 2011

Performance Standards

Lumenis ResurFX complies with:

- **IEC 60601-1** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- **IEC 60601-1-2** (Electromagnetic compatibility (EMC)
- **IEC 60601-2-22** ed3.0:2007 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- **IEC 60825-1**:2007 – Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide.

A detailed description appears in **Section 14**:

Summary of Technologies

The ***ResurFX module*** is a 1565nm fiber laser constructed on scanner operated by scanner controller.
The system may be activated by either handpiece or footswitch trigger.

Performance Data

The safety and efficacy of the ***ResurFX*** were established by a series of performance tests. Lab performance tests, design validation and software verification and validation. Validation, verification and testing have shown that the ***ResurFX*** device performs according to its specifications.

Summary of Clinical performance data

The Lumenis ***ResurFX*** was tested in bench performance tests to perform its intended use safely and efficiently. Lumenis has performed histological analysis to align between delivered energy and coagulation impact at the skin tissue level. Based on the equivalence with predicates, and on the histological analysis performed, Lumenis believes that clinical studies are not necessary to determine the safety and efficacy of the device.

Substantial Equivalence

Lumenis ResurFX device has the same intended use and indications as its predicate devices. The technology of the three predicates is also the same.
The envelope of power and frequency of the submitted ***Lumenis ResurFX*** is covered by the envelopes of its predicate devices. Any minor differences in the human interface and accessories design do not raise any new type of safety and effectiveness issues, as verified by performance testing. Therefore the ***Lumenis ResurFX*** is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Lumenis, Ltd.
% QSite
Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

September 3, 2013

Re: K130028
Trade/Device Name: Lumenis ResurFX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG
Dated: August 02, 2013
Received: August 06, 2013

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LUMENIS®

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K130028**

Device Name: ***Lumenis ResurFX***

Indications for Use: The ***1565nm ResurFX*** laser module is indicated for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off) for MXM
Division of Surgical Devices
510(k) Number: K130028
Neil R Ogden
2013.08.27 14:30:02 -04'00'